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Office Action Summary	Application No.	Applicant(s)
	10/707,135	TIBERIO, OSVALDO ANTONIO
	Examiner	Art Unit
	Keshia Gibson	3761

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.

Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)| | Responsive to communication(s) filed on _____.

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *7-9,12 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,10,11 and 14-20* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 November 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other. _____

Tiberio, Osvaldo Antonio

Cervical Cancer Screening Methods and Apparatus

Abstract

A disposable device for cervical and endocervical cell collection by a subject: female patient or any health care practitioner. This invention provides methods and apparatus for performing cervical cancer screening without the need for direct cervical observation, health care facilities or without the assistance of health professionals. This device includes a plastic tube closed on one end by a very thin membrane. This tube contains a plastic stick with a proximal enlargement for manipulation by the subject. On the distal end of the stick is inserted a bulb-shaped nylon brush. The subject inserts the device into the vagina, pushes the stick so as to allow the brush to break the membrane and enter in contact with the cervix, rotates the stick in order to collect a cell sample, draws the brush back into the tube and withdraws the whole device. The sample is then sent for analysis.

What is claimed is:

1. An Apparatus for the collection of free endocervical and cervical cells by the subject, a doctor or paramedic personnel, said apparatus comprising:

a- A cylindrical plastic tube, positionable within the vagina;
b-A cylindrical plastic stick, positioned within the plastic tube, with a 1.5 cm bulb-shaped nylon brush at its end.
c-An extra-thin membrane located within the interior of said tube, 1 centimeter from the end that is inserted in the vagina, and thinner in its central portion so as to be easily broken when required, and its parts remaining fixed to the interior portion of said tube.

Description

BACKGROUND OF INVENTION

[0001] Cervical cancer is the second most common cancer among women worldwide, and the leading cause of death from cancer in developing countries.

[0002] Annually, about 500.000 new cases of cervical cancer occur worldwide, and 80% of the cases do so in developing countries. These deaths are nearly 100% preventable, and early prevention is the key for the treatment of this disease.

[0003] Nowadays, prevention is reached through Papanicolaou (pap) smear. Pap screening is very easy, and only few minutes are necessary to perform it. The health care provider inserts a speculum into the vagina, holding the vaginal walls apart, and

takes a sample of endocervical and cervical cells from the cervix and around cervical fornix with an instrument (spatula, cotton swab, brush, etc.). This sample is placed on a glass slide, fixed with alcohol or cytological fixative, and sent to the pathologist for conventional analysis.

[0004] Nowadays, many types of brushes, spatulas, and cotton swabs are available to perform pap smears. However, these tests must be performed by health care providers (doctors, nurses, paramedics), which implies the obligation for female patients to attend medical offices or health care centers.

[0005] Unfortunately, all these means of collecting cell samples are insufficient when women fail to comply in scheduling regular visits to health care centers.

[0006] Indeed, the major issue remains patient's compliance with the screening. On the one hand, in developed countries, many women do not have regular screening tests for various reasons: lack of time, ignorance, fear, shame, difficult mobility, lack of medical insurance. On the other hand, in developing countries, most women do not have access to health centers.

[0007] Consequently, many women are not diagnosed and get to health centers at an advanced stage of the illness. Therefore, their state requires aggressive and expensive treatments, such as invasive surgeries, radiation therapy, chemotherapy, long-term hospitalization, and numerous medical consultations. Furthermore, in most cases, the patient's life expectancy and quality is likely to decrease whereas the cost for public health is increased.

SUMMARY OF INVENTION

[0008] The present invention relates to cervical cancer screening methods and apparatus.

[0009] The purpose of this new device is to allow women a better compliance with regular screenings: its use simplifies the pap test procedure and greatly reduces its cost, since medical offices or hospital facilities as well as qualified health personnel are no longer required to perform the endocervical and cervical cell collection. Indeed, in accordance with the present invention, the cell sample collection may be performed by women on their own, health care personnel (ex: nurses), technical health care providers (ex: lab technicians), doctors or any other trained persons. Moreover, the cell sample collection may be performed in the privacy of a home or in regions far off from health care centers.

[0010] Thus the use of this device allows to enhance women's compliance with recommended cervical cancer-screening protocols. Indeed, many women who do not comply in scheduling regular visits to health care centers because of their busy way of life may easily perform the test on their own. Furthermore, apart from women who have access to routine tests but do not comply with them, this device can be of use for all women who, for various reasons (fear, shame, ignorance, lack of health insurance or of economic means), do not usually attend health care centers, as well as for elderly female patients with decreased mobility.

[0011] Women are thus more likely to perform regular screenings on themselves thanks to the noninvasive, simple, private and economical procedure of the invention.

[0012] Furthermore, as the sample is collected without the need for direct cervical observation or access and without the assistance of a doctor or any health care provider, this system is useful for communities whose religious or other believes prevent women from attending health care centers, since one member of these communities may be instructed to perform the sample collection and collect a great amount of samples, later on analyzed in a lab.

[0013] The present invention may also be used in mass cervical cancer prevention campaigns, since health care personnel do not need highly complex health facilities to perform the endocervical and cervical cell collection.

[0014] In addition, self-screening kits produced in accordance with the present invention may be packaged for retail sale, thus containing the device, alcohol, spray or liquid-based cytology method. (According to every country's specificity), index card for patient's identification and directions for use. Likewise, said invention may be packaged for mass distribution (10, 50, 100, 500 units boxes), and contain cytological fixative (spray or liquid-based cytology method, according to every country's specificity), index card for patient's identification and directions for use. These kits would be of great help in developing countries where shortages of doctors prevent most women from receiving screening tests.

[0015] It stands to reason that, should the test results be positive or dubious, patients will have to attend health care centers to receive a final diagnosis, according to cervix cancer-detection protocols as established in health care centers.

[0016] In developing countries, or regions far off from health care centers, in case a positive result may occur, local health organizations will be responsible for transporting patients to health care centers in order to complete the tests and achieve a full diagnosis.

[0017] The present device is easy and inexpensive to manufacture, as well as easy to use and can therefore be made widely available to the consuming public.

[0018] Thus, millions of women who do not receive pap tests will have the chance to save their lives, for the benefit of the whole society.

[0019] Moreover, early detection, by allowing significant savings in the public health costs, is particularly important in developing countries where health budget is scarce. These savings may then be used on cancer or any other prevention campaign.

BRIEF DESCRIPTION OF DRAWINGS

[0020] Drawing scale: 1=1 cm.

[0021] FIGS. 1 & 2 are a series of cross-sectional views of the cell-collection device in accordance with an exemplary embodiment of the present invention.

[0022] Closed position (FIG. 1): Interior portion of the plastic tube (1a), external

portion (1b), stick (3), membrane (2), tip of the stick (5), bristles (4) of the bulb-shaped brush and proximal end of the stick (6).

[0023] Opened position (FIG. 2): The membrane is broken (2). Brush bristles expand (4).

[0024] FIG. 3 Is a cross-sectional view of the cell-collection device in accordance with an exemplary embodiment of the present invention, particularly illustrating the device positioned within the vagina (7) and in contact with the cervix (8).

[0025] Extraction position (FIG. 4).

DETAILED DESCRIPTION

[0026] The present device basically comprises two parts: A. An external part. This part is constituted by a 14 cm long by 1 cm wide plastic tube, the last 3 cm of the distal end being widened 1.5 cm (this end being introduced into the vagina).

[0027] The distal end of this tube is closed by an extra-thin membrane.

[0028] This membrane's function is twofold: it avoids the contamination of the brush placed inside the tube while this tube is inserted within the vagina and

[0029] it insures the device's dispensability: the membrane being broken, it is impossible to use the device a second time.

[0030] The proximal end of the tube has an orifice in which is inserted a stick. This orifice enables the stick's movement to be stable and serves as a stop for the stick so as to prevent its exceeding the edge of the tube and hurting the patient.

[0031] B. An internal part: The internal part has a 16.5 cm long by 4 mm thick internal stick, the last 1 cm of the distal end being widened 1.3 cm. This end is bulb-shaped and comprises 1 cm long nylon bristles fixed to it. These bristles form a 3.5 cm diameter bulb-shaped brush which will expand once breaking the membrane and collect the cell sample.

[0032] The proximal end is widened to insure easier manipulation and serve as a stop when entering in contact with to the tube to prevent stick's excessive forward movement.

[0033] In order to use correctly this device, the health care provider or the female patient herself must follow the following steps: The subject holds the tube and inserts its widest part deeply into the vagina.

[0034] Afterwards, the subject pushes the stick in order to break the tube's membrane. The brush will then enter in contact with the cervix.

[0035] The subject rotates the stick and consequently the brush. The brush bristles will rub the exocervix and part of the endocervix, thus collecting the cells.